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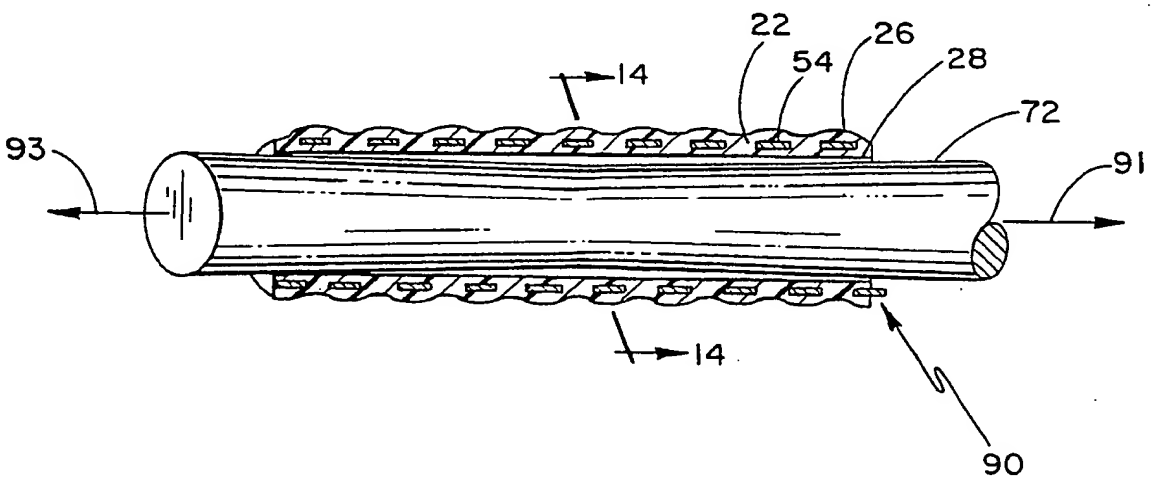

(57) Abstract

A kink resistant tubing (90) construction method. The kink resistant tube (90) is constructed by depositing a thin layer of encapsulating material (22) on a mandrel (72) creating a thin walled tube. A reinforcing coil (54) is then wound around the thin walled tube. A second layer of encapsulating material (22) may then be deposited on the reinforcing coil (54). The king resistant tube (90) is then removed from the mandrel (72) by first pulling on the ends of the mandrel (72) to shrink its diameter. The tubing (90) is processed at a precisely controlled temperature and humidity.

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KINK RESISTANT TUBING METHOD

This invention relates to a method of constructing a kink resistant tubing with an encapsulated reinforcing coil.

BACKGROUND OF THE INVENTION

Kink resistant tubing finds application as a material to construct medical catheters for infants, children and adults. The main application of catheters is for central venous access. Central venous access can be used for the administration of drugs, fluids or the monitoring of pressures. Administration of drugs implies the use of intravenous fluids, continuous drips or boluses of drugs.

There are different routes of placing catheters in infants and children. The first route of central access in a neonate is an umbilical artery catheter or venous catheter. Catheters are placed into umbilical artery or vein, in the remaining stump of the umbilical cord in the infant. Such a catheter can be used for monitoring blood pressure, central venous pressure, administering life sustaining drugs, or delivering IV fluids. Other routes of catheterization include the wrist or a radial artery. Usually drugs are not given by this route. In older children, after the neonatal period, the femoral artery and vein can be used, or the right internal jugular veins. Another route less commonly used in children, but nonetheless very useful for treating adults and teenagers, is the subclavian vein for central monitoring.

In addition to routine monitoring and drug administration, these catheters may also be employed in a procedure known as cardiac catheterization. This is a procedure by which pressures of the heart

can be monitored as well as blood withdrawal from the catheter to measure oxygen tension and Ph in the chambers of the heart. Oxygen tension is the oxygen saturation and the partial pressure of oxygen in blood samples in the various chambers of the heart. These catheters can be advanced into the heart through either a femoral route, which is the most common router, or through a vein in the arm known as the brachiocephalic.

Another application for catheters is blood withdrawal. Catheters placed in arteries or central veins are convenient routes for blood withdrawal.

Prior art catheters for central venous access and cardiac catheterization consist of tubes made of a plastic tubing of a pliable plastic. The plastics come in different types that have various degrees of pliability depending upon the temperature. These catheters are usually fairly stiff at room temperature but become very soft as they are exposed to body temperature.

Plastic catheters of the prior art have many disadvantages. As noted above, they are fabricated from plastics which often soften when inserted into a body. As a result, such catheters become more difficult to manipulate. Such prior art catheters have a tendency to kink and buckle when they become pliable while implanted in blood vessels. The mechanism of failure includes kinking which may occur, for example, when the catheter butts up against the wall of a vessel. Such catheters may also kink by folding back on itself while being advanced into a vessel. When a catheter kinks it is no longer able to transport drugs or IV fluids into the vessel. Kinking also effects the withdrawal of backblood from the catheter. Methods of remedying an obstructed catheter can consist of flushing the

catheter with a bit of high pressure fluid to try to remove the kink. If the kinking is severe enough, the catheter must be removed and replaced with a new one. Unfortunately, life-threatening conditions can occur from a kinked catheter, as, for example, in the event that the obstruction of flow of a life sustaining drug to the patient is obstructed by kinking.

Long-term catheters such as the Hickman and Broviac catheters are implantable catheters that are implanted under the skin into central veins, usually through a subclavian route or an internal jugular route, and occasionally through a femoral route. These catheters are also implanted in an area near the neck where they can be kept clean. These catheters are implanted on a permanent basis. They are usually used for patients with chronic illnesses, such as, for example, in the case of children who receive chemotherapy.

Use of catheters in adults parallels many of the pediatric uses discussed above. Catheters can be placed for temporary and permanent use in jugular and subclavian vessels. Catheters can also be made for use in cardiac catheterization. Small bore catheters such as those provided by the instant invention enjoy a distinct advantage over larger bore catheters because they can form certain shapes for use in areas such as cardiac coronary catheterization.

It is therefore a motivation of the invention to provide a kink resistant tubing that can be used in medicine and allied fields. It is also a motive of the invention to provide a catheter that avoids the potentially hazardous problem of collapsing within a body vessel.

SUMMARY OF THE INVENTION

A kink resistant tubing construction method is

provided that is used to make a kink resistant tubing out of a thin wall polymer and metal or fiber composite. The kink resistant tubing method of the invention starts by depositing a thin layer of encapsulating material on a mandrel creating a thin walled tube. A reinforcing coil is then wound around the thin walled tube. A second layer of encapsulating material may then be deposited on the reinforcing coil. The kink resistant tube is then removed from the mandrel by first pulling on the ends of the mandrel to shrink it's diameter. The resulting kink resistant tube exhibits superior kink resistance when subjected to severe bending stress. The kink resistant tubing also has a thin wall thicknesses in comparison to tne prior art.

Other objects, features and advantages of the present invention will become apparent to those skilled in the art through the description of the preferred embodiment, claims and drawings herein where like numerals refer to like elements.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A shows an idealized schematic of the kink resistant tubing apparatus of the invention.

Figure 1B shows the kink resistant apparatus of the invention in an idealized cross-sectional schematic.

Figure 2A shows a schematic of one example of the kink resistant tubing apparatus of the invention

Figure 2B shows one example of the kink resistant tubing apparatus of the invention in a cross section shown using a thin wall encapsulation method with a cut away of reinforcing coil supports.

Figure 3 shows a schematic of one example of kink resistant tubing as provided by the invention showing a plurality of reinforcing coils.

Figure 4 shows one example of the kink

resistant tubing of the invention with a cross-sectional view of the thin wall incorporating a composite fiber reinforcement.

Figure 5 shows an isometric isolation view of a supporting coil as employed in one embodiment of the invention.

Figure 6 shows an isometric view of the thin wall kink resistant tubing apparatus of the invention incorporating a reinforcing coil.

Figure 7 shows the first step of manufacturing the apparatus of the invention with a mandrel coated with a thin layer of encapsulating material with the encapsulating material cut away.

Figure 8 shows a cross-section of a mandrel as employed by the method of the invention with a thin layer of encapsulating material.

Figure 9 shows a mandrel and a thin layer of encapsulating material as employed by the method of the invention with a cut away of the coil wound around the thin layer of encapsulating material.

Figure 10 shows a kink resistant tubing cross-sectional diagram with a reinforcing coil wrapped around the thin encapsulating layer around the mandrel as employed by one method of the invention.

Figure 11 shows the apparatus of the invention in its final constructed state on the mandrel.

Figure 12 shows a cross-section of the mandrel with the apparatus of the invention in final constructed state.

Figure 13 shows the method of removing the kink resistant tubing apparatus of the invention from a mandrel.

Figure 14 shows the kink resistant tubing apparatus being removed from the mandrel in a cross sectional view.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Now referring to Figure 1A which shows a isometric view of one embodiment of the kink resistant tube of the invention. The kink resistant tube 10 is comprised of an ideally substantially circular inside wall 18 and an outside wall 16, which is ideally substantially perfectly smooth. Tube 10 is composed of encapsulating material 12 and an encapsulated coil 14 shown in Figure 1B.

Now referring to Figure 1B which shows a cross-sectional diagram of the tubing apparatus of the invention shown in Figure 1A. Figure 1B shows a thin walled kink resistant tube 10 constructed of an encapsulating material 12 containing a spiral wound reinforcing coil 14. Figure 1B shows a cross-section of the tube 10 showing substantially half of the tube 10. In one embodiment of Figure 1B the outside wall 16 is substantially smooth and parallel to the inner wall 18.

Now referring to Figure 2A which shows one embodiment of the apparatus of the invention which is manufactured with the kink resistant tubing construction method of the invention. The kink resistant tubing 20 has a ribbed surface 26 and walls 22. The walls 22 contain a reinforcing material 24 as shown in Figure 2B. The ribbed surface 26 comprises a plurality of ribs 25. The ribbed surface 26 closely follows the contours of the reinforcing material 24 embedded within the walls 22 of the kink resistant tubing 20. The kink resistant tubing 20 has a substantially smooth inside wall 28 through which various fluids may pass. Each of the plurality of ribs 25 is comprised of an encapsulating material around embedded reinforcing members 24.

Now referring to Figure 2B which shows the kink resistant tubing of Figure 2A in cross-section.

The reinforcing members 24 are embedded in a thin encapsulating material 22. The reinforcing members 24 in the example embodiment of Figure 2B are advantageously comprised of a spiral wound rectangular cross-section metallic spring which is wound around and within the encapsulating material 22. Figure 2B also shows the plurality of ribs 25 of the outer surface 26 of the kink resistant tubing 20.

The strength and versatility of the kink resistant tube 20 is illustrated by the cross-section in Figure 2B. The tubing is better able to withstand the hoop stresses of any internal pressure indicated by pressure arrows P on the tube wall 28. The hoop stress in the tube encapsulating material 22 is transferred to the reinforcing members 24. Those skilled in the art will recognize that the reinforcing members could either be a spiral wound spring-like structure or could be separate, individual rings independent of each other. The quality of the reinforcing material is advantageously such that the radial hoop stress is substantially adsorbed continuously radially around the tube by the reinforcing member.

Now referring to Figure 3 which shows the kink resistant tubing apparatus of the invention in a two-dimensional projection with the reinforcing members 34 in a top down view. Figure 3 also shows the outside surfaces 26 of the kink resistant tubing 30. Encapsulating material 22 comprises the material between the reinforcing members 34. The reinforcing members 34 can alternately be comprised of coiled wire made of various sizes and shapes. The encapsulating material 32 is used for the total encapsulation of the reinforcing coil 34, as the elastomeric medium and for providing a smooth internal and external surface.

The materials of choice for the kink resistant tubing 30 are elastomers such as polyurethane or silicone rubber. Different materials will result in various levels of flexibility and kink resistance. Those skilled in the art will also recognize that when increased torque is applied to the kink resistant tubing 30 additional reinforcement in the form of multi-wire braiding, multi-filer windings and other metallic or nonmetallic reinforcement may be used.

After extensive testing in the laboratory certain materials and material types had shown particular suitability to use in the kink resistant tubing encapsulating material. Table A lists these materials and tradenames as well as which manufacturers they are available from.

TABLE A

MATERIALS	MANUFACTURES (TRADE NAMES)
(A) polyesterurethane:	B.F. Goodrich (Estane) DuPont (Hytrel)
(B) polyetherurethane:	Dow (Pellathane) B.F. Goodrich (Estane)
(C) aliphatic polyurethane:	Thermedics (Tecoflex)
(D) polyimide:	DuPont (Pyraline)
(E) polyetherimide:	General Electric (Ultem)
(F) polycarbonate:	Mobay (Apec)
(G) polysiloxane:	Dow Corning (Silastic) Dow Corning (MDX-4159)
(H) hydrophilic polyurethane:	Grace Co. (Hypol)
(I) polyvinyls:	
(J) Latex:	
(K) hydroxy-ethyl methacrylate:	
(L) blends of the above materials:	

(M) most any other elastomer that can be carried in solvent:

The above-listed materials when used alone or as components to a blend of materials displayed the best performance in tubing manufactured by Navarre Laboratories Ltd. of Minnesota. The subsequent products produced with these materials allow for a range of performance characteristics. Some of the blends of materials are discussed hereinbelow offered specific performance advantages.

Those skilled in the art will appreciate that the materials described above have application in the manufacture of medical devices including tubing in the prior art. When manufactured into prior art devices the listed materials have displayed superior performance characteristics. The materials have found uses in guidewire coating, Laparotomy/Cholecystectomy devices, vascular probes, peripheral and coronary catheters, vascular access catheters, and ophthalmic devices.

In the present kink resistant tubing apparatus of the invention these materials have been successfully used for the first time to manufacture both the thin walled inner tube and the outer encapsulating tube. These materials have been prepared with a solvent system material manufacturing process according to the following proportions listed

in Table B. The materials listed herein are by way of illustration and not by way of limitation. Similar materials known to those skilled in the art having equivalent properties may also be used.

TABLE B

(A) urethanes:	solids:	6% to 14%
	solvents:	THF/DMF 85/15 (THF- Tetrahydrofuran, DMF- Dimethylformamide)
	viscosity:	10-100 centiStokes
(B) polyimide:	solids:	20% - 45%
	solvents:	N-Methylpyrrolidone
	viscosity:	80-1000 centiStokes
(C) polyetherimide	solids:	8% to 12%
	solvents:	methylene chloride
	viscosity:	40-100 centiStokes
(D) polycarbonate:	solids:	6% to 12%
	solvents:	THF/DMF 85/15
	viscosity:	10-60 centiStokes
(E) polysiloxane:	solids:	30% - 60%
	solvents:	111-trichloroethane
	viscosity:	100-450 centiStokes
(F) hydrophilic polyurethane:	solids:	.1% - 95%
	solvents:	water
	viscosity:	not applicable

Having described the apparatus of the invention, the method by which the apparatus is fabricated will now be described in detail. The preparation of the kink resistant encapsulating materials is accomplished by following a series of steps. The preparation process is similar for all materials. The solid or liquid material is first weighed. The solvent is then prepared. The solvent is added to the solid or liquid material in the

appropriate amount to make the desired percent solids. Stirring is necessary to completely solvate plastic materials. Once the plastic is completely in solution the material is ready for use in coating applications for the kink resistant tubing of the invention.

The encapsulating material 22 is configured to substantially cover the reinforcing members 34. Those skilled in the art will recognize that if a reinforcing coil is found that has excellent bio-compatibility qualities that the tubing coil may not need encapsulation.

Various different types of encapsulating materials can be used to manufacture the kink resistant tubing encapsulating material. Those include, but are not limited to, polyurethane, silicone rubber, polyurethane/polycarbonate blends, polyurethane/silicone blends, polyvinylchloride, polyimide and latex.

Now referring to Figure 4 which shows another example of the kink resistant tubing apparatus of the invention in an enlarged cross-section diagram. The kink resistant tubing 40 has the encapsulating material 42 which in this example embodiment of the invention is advantageously substantially comprised of silicone rubber. The reinforcing members 44 comprise a composite wound fiber 44 which comprise the composite tubing's 40 coiled reinforcement member. The outer surface 26 of the composite tube 40 is formed by the encapsulating material 42.

Now referring to Figure 5 which shows a schematic isometric drawing of an example of a reinforcing coil 50. The reinforcing coil 50 in the kink resistant tubing apparatus of the invention provides radial strength and hoop strength. The reinforcing coil 50 helps retain the circularity of

the tubing 10 and thereby avoids buckling and kinking of the tubing 10. The reinforcing coil 50 also provides a crush-resistance to the reinforcing coil. The reinforcing coil 50 comprises a wire or fiber 54 which may have various cross-sectional shapes, such as, for example, rectangular, circular, or elliptical. Those skilled in the art will recognize that the cross-sectional shapes will effect the load bearing characteristics and strength characteristics of the reinforcing coil 50. In the example of Figure 5 the cross-section 52 is rectangular with a flat face 56 and flat body 58.

Various different reinforcing coil 50 materials may be used. Further, the reinforcing coil dimensions can vary as well as the reinforcing coil 50 pitch and diameter. Listed below in Table C are some of the alternative coil 50 design parameters that can be used.

TABLE C

Coil Wire Size:	0.001-0.015
Coil Wire Material:	metals; stainless steel, MP35, NiTi, Tungsten, Platinum, kevalar, nylon, polyester, acrylic
Coil Pitch:	1-5 times maximum coil wire dimension
Coil Diameter:	0.010-0.375 inches

Referring now to Figure 6, an isometric view of one embodiment of the kink resistant tubing 60 of the invention is shown using a wire or fiber 54. The kink resistant tube 60 construction method comprises four major steps listed in Table D. These four major process steps are described in detail below with reference to Figures 7-14.

TABLE D

1. Mandrel Coating
2. Coil Wrapping of Mandrel Substrate
3. Over coating the coiled assembly
4. Mandrel Extraction

Now referring to Figure 7 which shows a mandrel 72 with a thin film encapsulating material 74. In Figure 7 the encapsulating material 74 is shown in a cut away view. The mandrel 72 provides the internal dimensions of the kink resistant tubing. The mandrel may be advantageously constructed from a fluoropolymer such as PTFE or FEP, polyethylene, nylon, or possibly a ductile metal such as silver. The mandrel 72 may be tubular or solid and may advantageously diametrically reduced upon the application of sufficient stretching force. If a tubing is used for the mandrel 72, a support rod, usually metallic, can be used to provide increased straightness and stiffness.

The mandrel is coated with a thin layer or layers of the encapsulating material 74 in solution form, using the solution draw process described below. This can require one to several coats depending on tubing specifications and encapsulating material 74 viscosity. Typically inner layers are coated to thicknesses of 0.0005-0.005 inches. Solution draw rates of 6-18 inches per minute are used to apply the encapsulating material 74.

The solution draw process is comprised of a number of steps. The first step is to prepare the encapsulating material in a solution form. The mandrel 72 is drawn through the solution of the encapsulating material 74. The solution is held in a container and the container contains a hole slightly larger than the size of the mandrel. The

mandrel is then drawn through the solution and the encapsulating material 74 is deposited on the mandrel 72. The resulting encapsulating material thickness is highly controllable due to the propensity of the encapsulating material to adhere to the mandrel 72.

Now referring to Figure 8 which shows a cross sectional diagram of the mandrel 72 and thin coating of encapsulating material 74. After the proper thickness of encapsulating material 74 has been applied, the mandrel and encapsulating material 74 must be cured at room temperature for 6-8 hours. This allows total solvent evaporation.

The process variables for step one (mandrel coating) are summarized as follows in Table E.

TABLE E

Environmental	
Ambient temp:	65°F-76°F
Humidity:	10-35% relative
Solution Viscosity:	1-100 centistokes
Solution Draw Rate:	6-18 inches per minute
Solvent Evaporation Rate:	14.5 using NButylacetate standard
Solution Temp.	65°F - 76°F
Solution Chemistry	6% - 14% solids (Such as Polyurethane in solution with highly polar solvents.)

The coil wrapping process involves wrapping the reinforcing coil wire 54 at the proper tension and pitch. The coil wire is wrapped around the coated mandrel 72 encapsulating material substrate uniformly to the desired specifications. The coil's material composition, rotational speed, tension, substrate

diameter and pitch determine the size and flexibility of the coil.

Now referring to Figure 9 which shows the method of constructing the reinforcing coil 54 on the encapsulating material substrate 74. The coil 54 in one embodiment of the invention is wrapped around the mandrel 72.

Now referring to Figure 10 which shows a cross section of a kink resistant tube being constructed from the method of the invention. The coated mandrel substrate 74 is placed and secured in the coil wrapping apparatus 73. The coil wrapping apparatus 73 may be any suitable coil wrapping machine such as, for example, an Accuwinder (TM) machine as manufactured by the Accuwinder Company of California. The coil wire 54 must adhere to the lead end of the mandrel substrate 75 and allowed to cure. The substrate 74 is then wrapped from end to end using the predetermined coil wrapping parameters. Once the coil wrap is complete, the coil 54 must be locked or secured to the coated mandrel substrate 74 using adhesives. This is done at a coil termination 77. After the adhesive has cured, the wire 54 can be cut and the coiled substrate removed from the machinery 73.

The process variables for the coiling operation include the wire wrapping speed and coil wire tension. Experimental trials have determined that the wrapping speed should be between about 500 and 4000 rpm and the coil wire tension should be between about 25 and 200 grams.

Now referring to Figure 11 which shows the method of the invention used to apply an over coating to the coil assembly. The coil 54 is over coated to a predetermined thickness using the solution draw process described above. The process variables used

in the solution draw of the encapsulating material are discussed above.

Now referring to Figure 12 which shows the coil 54 assembly over coated to the predetermined thickness. The solution draw process has covered mandrel 72 forming kink resistant tubing 90 with encapsulating material. The surface 26 of the tubing 90 is formed by the outside of encapsulating material 22 solidifying around the reinforcing coil 54.

Now referring to Figures 13 and 14 which show the method of the invention used to extract the mandrel 72 from the kink resistant tubing 90. Once the kink resistant tube assembly 90 has been fully cured, the final step is to extract the mandrel 72. This is done by securing each exposed termination of the mandrel 72 and applying sufficient and directionally opposite forces indicated by directional arrows 91 and 93 to plastically reduce the diameter of the mandrel 72 by 10-50%. Once this is accomplished, the mandrel 72 can simply be removed from the tubing assembly.

The invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment details and operating procedures, can be accomplished without departing from the scope of the invention itself.

What is claimed is:

CLAIMS

1. A method of constructing a kink resistant tube (10, 20, 30, 90) around a mandrel (72) comprising the steps of:
   (a) coating the mandrel (72) with a thin layer of encapsulating material (12, 32, 42);
   (b) depositing a means for reinforcement (34, 50) around the encapsulating material (12, 32, 42); and
   (c) removing the mandrel (72) from within the thin layer of encapsulating material (12, 32, 42).

2. The method of claim 1 further comprising the step of coating the reinforcing material (34, 50) with an encapsulating material (12, 32, 42).

3. The method of claim 1 wherein the step of depositing a means for reinforcement (34, 50) around the encapsulating material (12, 32, 42) further comprises winding a wire (44, 54) around the encapsulating material (12, 32, 42).

4. A kink resistant tubing (10, 20, 30, 90) manufactured in accordance with the process of claim 1.

5. A kink resistant catheter tubing (10, 20, 30, 90) manufactured in accordance with the process of claim 1.

6. A kink resistant tubing (10, 20, 30, 90) manufactured in accordance with the process of claim 2.

7. A kink resistant catheter tubing (10, 20, 30, 90) manufactured in accordance with the process of claim 2.

8. The method of claim 3 wherein the wire (44, 54) is spirally wound around the thin walled tube (10, 20, 30, 90).

9. The method of claim 3 wherein the wire (44, 54) forms rings around the thin walled tube (10, 20, 30, 90).

10. The method of claim 3 wherein the wire (44, 54) substantially comprises a metal wire (44, 54).

11. The method of claim 3 wherein the wire (44, 54) consists of a material selected from the group consisting of stainless steel, MP35, NITi, tungsten, platinum, kevalar, nylon, polyester and acrylic.

12. The method of claim 3 wherein the wire (44, 54) has a cross section (52) and the cross section shape is substantially rectangular.

13. The method of claim 3 wherein the wire (44, 54) has a cross section and the cross section shape is substantially circular.

14. The method of claim 1 wherein the encapsulating material (12, 32, 42) is made from a material selected from the group consisting of polyesterurethane, polyetherurethane, aliphatic polyurethane, polyimide, polyetherimide, polycarbonate, polysiloxane, hydrophilic polyurethane, polyvinyls, latex, and hydroxy-

ethyl methacrylate.

15. The method of claim 2 wherein the encapsulating material (12, 32, 42) is made from a material selected from the group consisting of polyesterurethane, polyetherurethane, aliphatic polyurethane, polyimide, polyetherimide, polycarbonate, polysiloxane, hydrophilic polyurethane, polyvinyls, latex, and hydroxy-ethyl methacrylate.

16. The method of claim 1 wherein the mandrel (72) has two opposing ends and the step of removing the mandrel (72) further includes:
(a) pulling on the opposing ends to reduce the mandrel diameter (72); and
(b) removing the mandrel (72) from within the thin layer of encapsulating material (12, 32, 42).

17. The method of claim 2 wherein the mandrel (72) has two opposing ends and the step of removing the mandrel further includes:
(a) pulling on the opposing ends to reduce the mandrel diameter (?); and
(b) removing the mandrel (72) from within the thin layer of encapsulating material (12, 32, 42).

18. The method of claim 1 wherein the construction of the kink resistant tube (10, 20, 30, 90) is carried out in an ambient temperature and the ambient temperature is in a range from 65°F to 76°F.

19. The method of claim 1 wherein the construction of the kink resistant tube (10, 20, 30, 90) is

carried out in a space having a relative humidity in a range from 10% to 35%.

20. The method of claim 1 wherein the encapsulating material (12, 32, 42) has a solution viscosity in a range from 1 to 100 centistokes.

21. The method of claim 1 wherein the step of coating the mandrel (72) further comprises drawing the mandrel (72) through the encapsulating material (12, 32, 42) at a rate in the range of 6 to 18 inches per minute.

22. The method of claim 1 wherein the encapsulating material (12, 32, 42) is held at a temperature in the range of 65°F to 76°F.

23. The method of claim 3 wherein the wire (54) size ranges from 0.001 inches to 0.015 inches.

24. The method of claim 3 wherein the wire (54) forms a coil (34, 50) and the coil (34, 50) has a pitch ranging from 1 to 5 times the maximum wire dimension.

25. The method of claim 3 wherein the wire (54) forms a coil (34, 50) and the coil (34, 50) has a diameter from 0.010 inches to 0.375 inches.

Fig.-1A

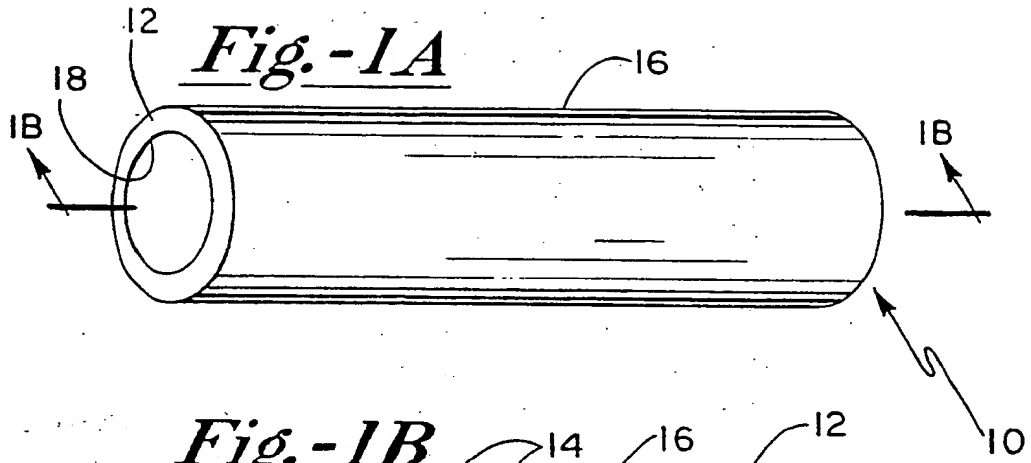


Fig.-1B

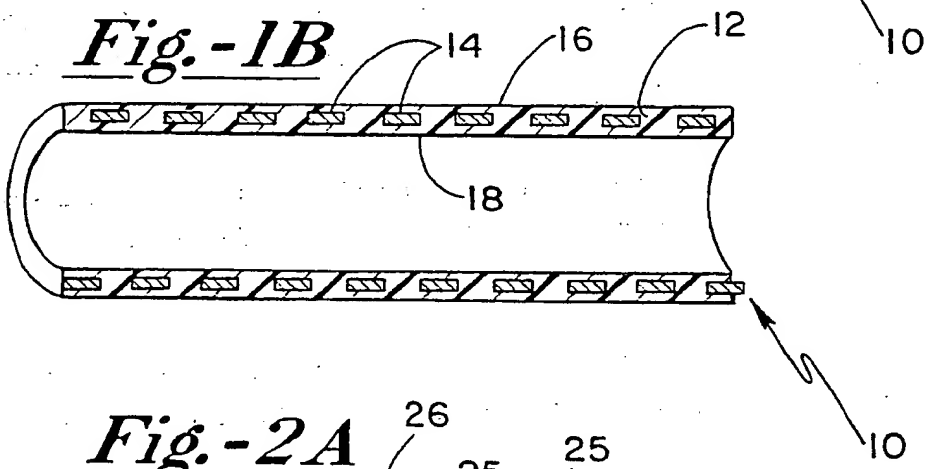


Fig.-2A

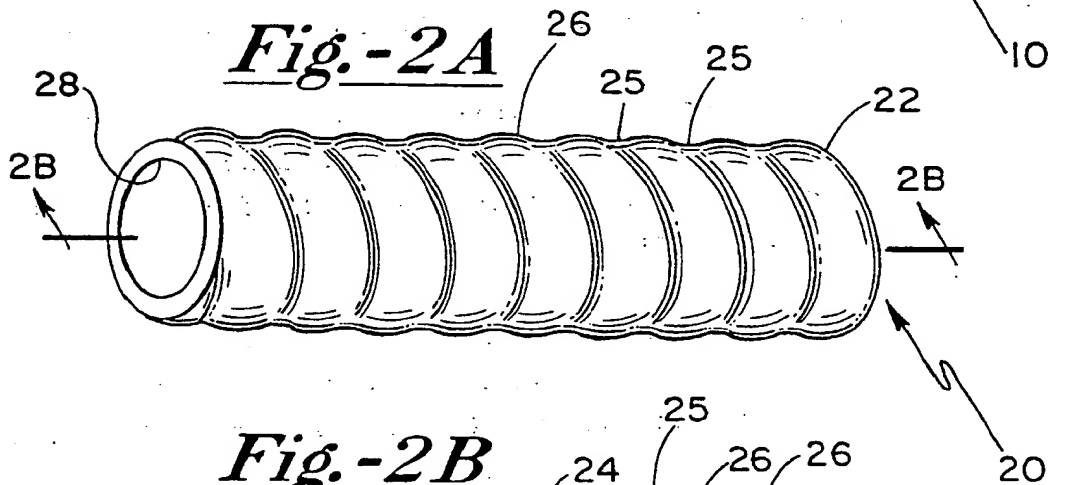


Fig.-2B

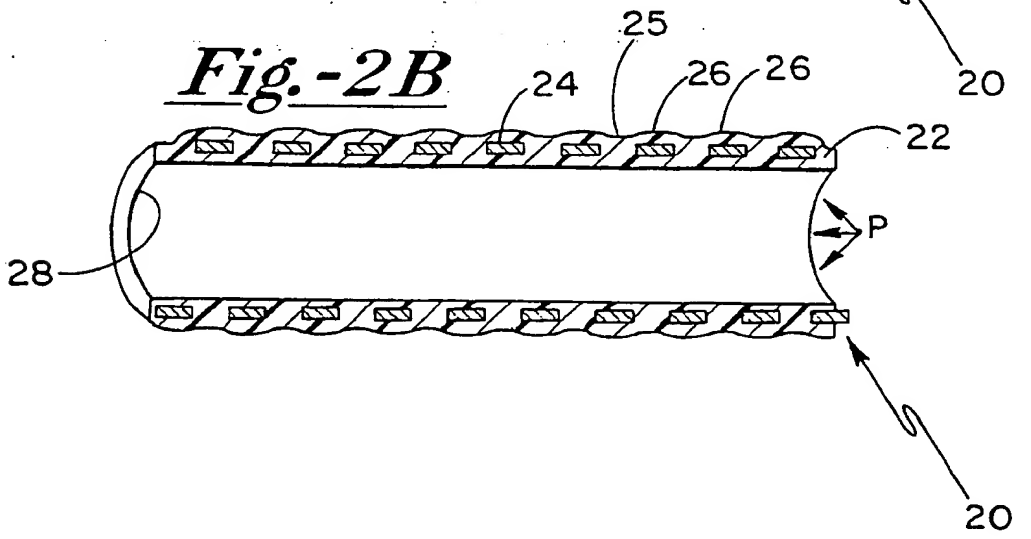


Fig.-3

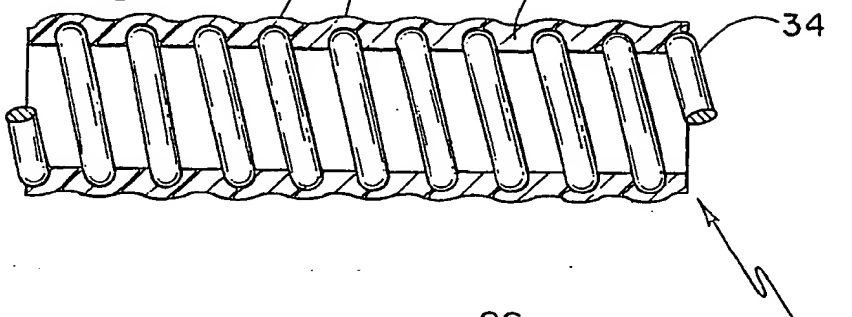


Fig.-4

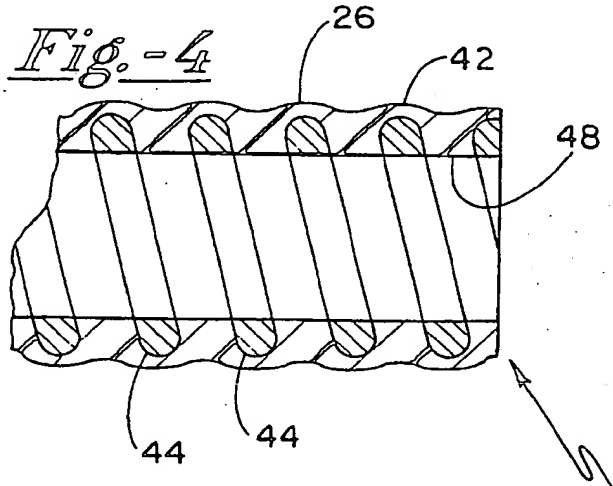


Fig.-5

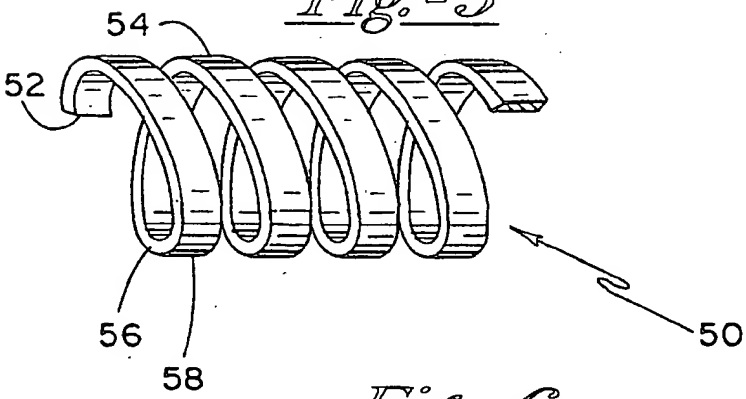


Fig.-6

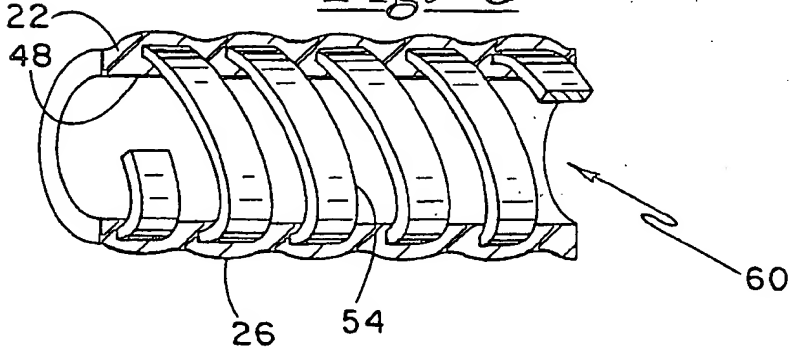


Fig.-7

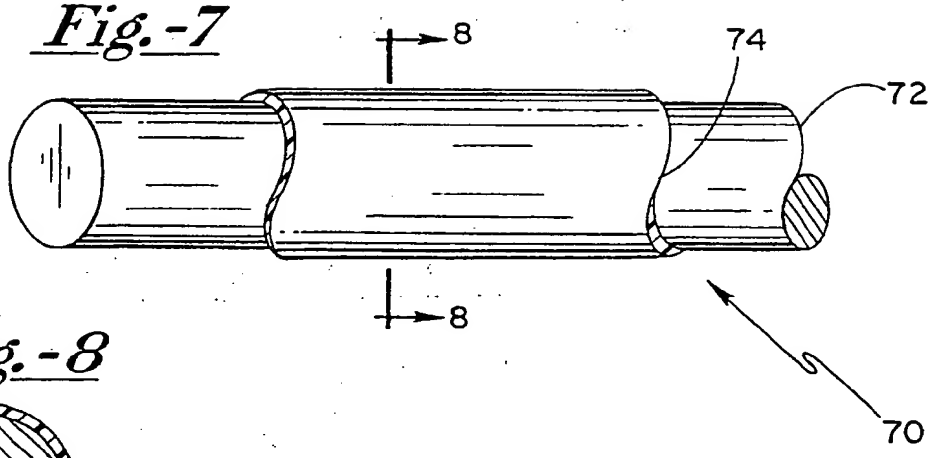


Fig.-8

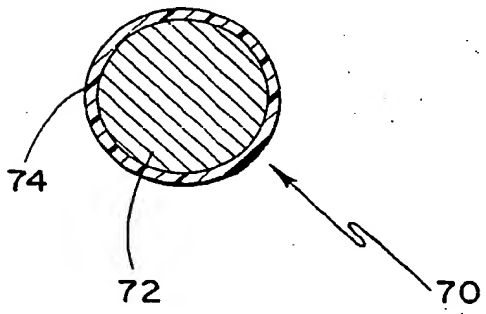


Fig.-9

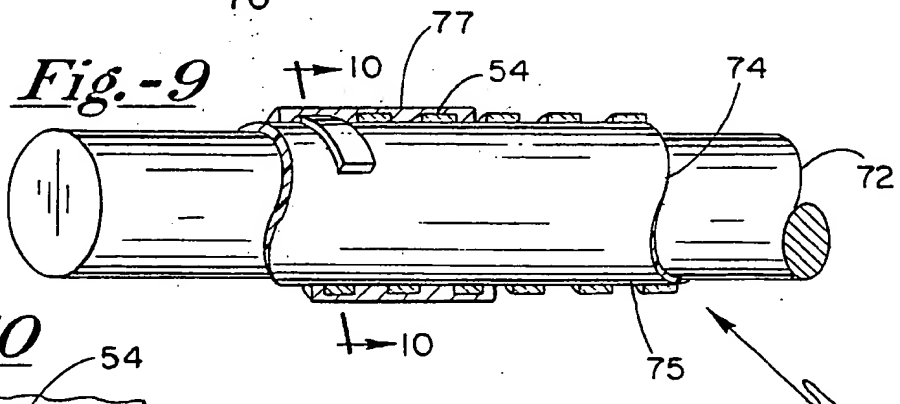


Fig.-10

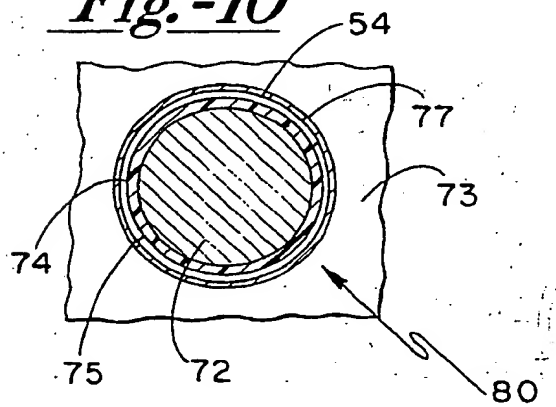


Fig.-11

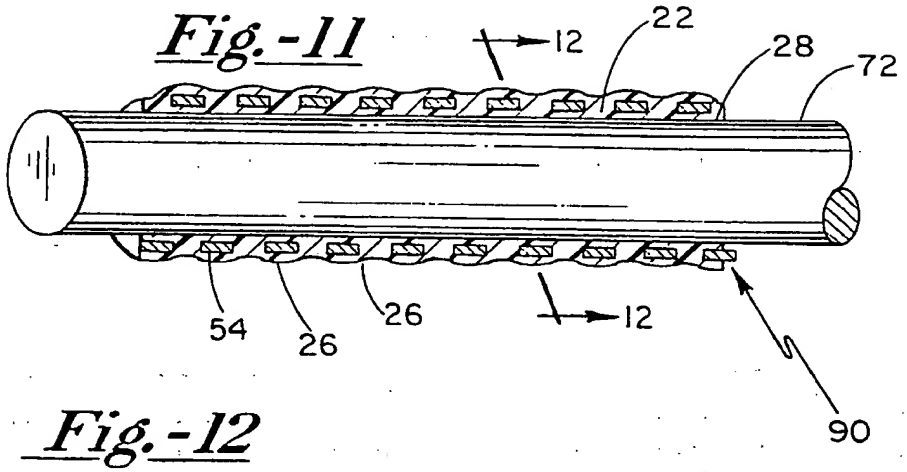


Fig.-12

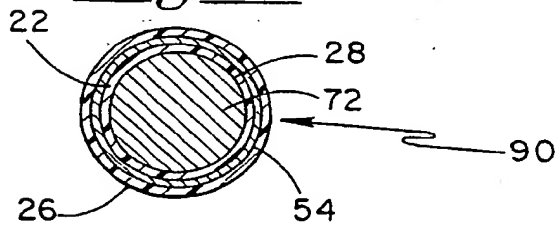


Fig.-13

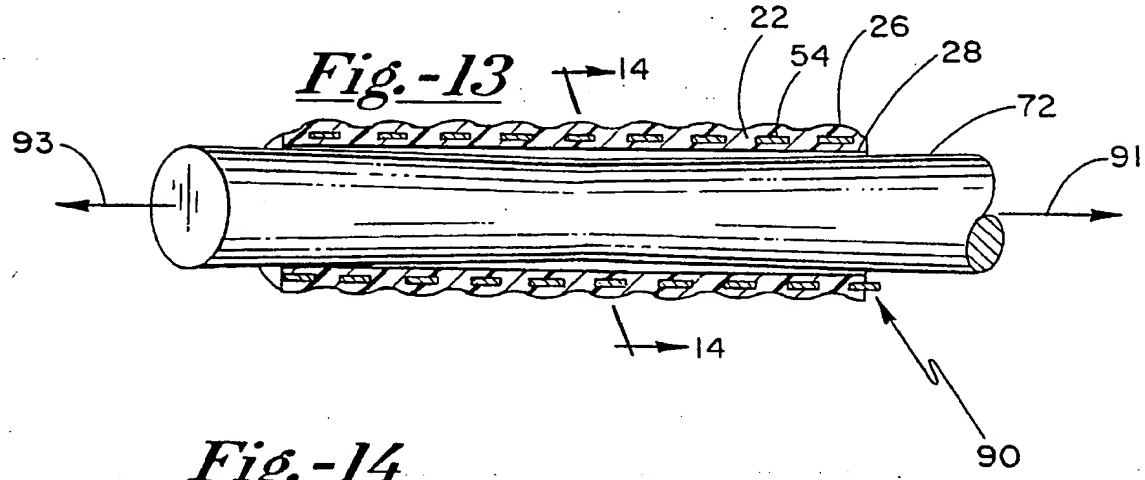
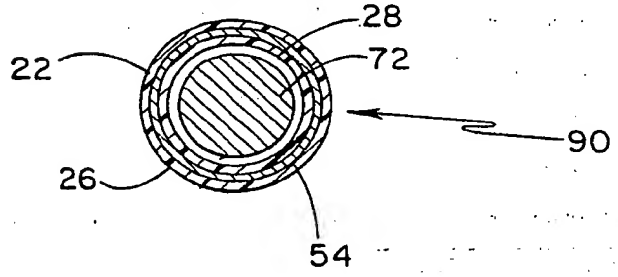


Fig.-14



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/01310

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : B23P 17/00; A61M 25/00
US CL : 29/527.4, 423, 458; 604/282

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : U.S. 29/527.4, 423, 458, 460, 527.1, 527.2; 604/282; 128/4, 6; 74/502.5

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US, A, 3,485,234 (Stevens) 23 December 1969, see col. 2, lines 56-72 and col. 3, lines 1-18.	1, 2, 4-7 and 14-17 1-25
Y	US, A, 5,019,057 (Truckai) 28 May 1991, see entire disclosure.	1-25
Y	US, A, 4,634,432 (Kocak) 06 January 1987, see col. 5, lines 29-40.	21
X	US, A, 5,059,375 (Lindsay) 22 October 1991, see col. 1, lines 56-62.	1-8, 10, 14, 15
A	US, A, 3,865,776 (Gergen) 11 February 1975, see entire disclosure.	

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 APRIL 1993	01 JUN 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer S. THOMAS HUGHES Telephone No. (703) 308-1148

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